UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA ex rel. LAURIE SIMPSON, Plaintiff, v. BAYER CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER HEALTHCARE LLC; and BAYER AG, Defendants.	Civil No. 05-3895 (JLL) (JAD) ***Document Filed Electronically*** ***Oral Argument Requested***

RESPONSE IN OPPOSITION TO PLAINTIFF-RELATOR'S CROSS MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

As Relator's brief confirms, the Government's fixed-fee payment system is dispositive of her Trasylol causes of action. Relator makes no argument and presents no evidence that any hospital ever submitted any claim for payment for Trasylol. Nor does she make any argument or cite any evidence that the Government ever paid a single penny for Trasylol.

To the contrary, as the Government makes clear, Trasylol is not even "identified on the inpatient claim," and the Government paid the same amount for a surgery regardless of whether the hospital used Trasylol. *See* CMS Letter at 1–2 (Lustberg Decl. Ex. A). Under the fixed-fee system, the Government did not know when Trasylol was being used, and the Government did not care whether Trasylol was being used, because the Government paid the same fixed fee for the surgical procedure either way. Because Relator has identified no materially false claim—or any claim at all for Trasylol—this Court should grant partial summary judgment to Bayer.

Relator argues that DRG claims, which do not mention Trasylol, support her position, but numerous indistinguishable cases have rejected this argument. This Court should do the same for three reasons. First, the DRG claims were for surgical procedures, not for Trasylol, which was not even referenced on the claim forms. Trasylol was a cost *borne by the hospitals*, much like light bulbs, surgical gloves, or

other materials used during the surgery. The hospitals did not submit a claim for payment for Trasylol.

Second, Relator identified nothing false in the DRG claims, which make no representations about Trasylol, let alone false ones. Relator's unstated assumption is that whenever a hospital submits a DRG claim, it is implicitly providing a certification with regard to the products that were used in the medical procedure—even though these products are not identified on the claim form and not paid for by the Government. Relator cites no authority for this novel and overbroad position, which is inconsistent with Supreme Court precedent identifying the scope of implied certifications, as well as with the purpose of the False Claims Act, which is to protect the Government fisc.

Third, even if there were a false claim (and there was not), it was immaterial as a matter of law. The purported kickbacks and false statements had no impact on the treasury because the Government paid the same amount for the surgery regardless of whether Trasylol was used. Indeed, the Government did not even know whether Trasylol was used because the drug was not identified on the DRG claim form. Relator ignores the fundamental distinction between products that appear on the claim form and could affect the Government's payment decision, and those that do not and could not.

For these reasons, Relator's Trasylol case fails as a matter of law. Well aware that her legal arguments are meritless, Relator sprinkles her brief with footnotes asserting theoretical exceptions to the fixed-fee payment system, such as outlier payments. But Relator has presented no evidence of any outlier payments or anything else that might support her theoretical exceptions. To survive summary judgment, a party needs evidence, not mere allegations or bald assertions. Bayer has repeatedly asked Relator—both in discovery and in the recent Court conferences—for any evidence that supports her allegations, and she identified nothing.

This, of course, was why the parties agreed that the fixed-fee payment system presents a pure legal issue ripe for this Court's resolution, and why the parties filed cross-motions for summary judgment. Relator's belated attempt to re-inject factual disputes should not be permitted. This case has been on the Court's docket for over a decade, and Relator has no basis to prolong the litigation regarding Trasylol. The Court should grant partial summary judgment to Bayer.

BACKGROUND

The mechanics of the Government's fixed-fee policy are undisputed. As Relator concedes, "Medicare reimbursed hospitals for items and services provided to beneficiaries during inpatient stays through fixed, bundled payments under the Inpatient Prospective Payment System." Rel. Mot. at 5. This "fixed, bundled" payment was "based upon the Diagnosis Related Group ("DRG") classification of

the inpatient stay, rather than on the costs of the specific items and services provided to the particular patient." Rel. SOF ¶ 6. Relator likewise acknowledges that "State Medicaid programs also utilized some form of prospective payment system for inpatient services during the Relevant Time Period." Rel. Mot. at n.8.

The parties thus agree that the Government paid for the surgical procedures in which Trasylol was used on a fixed-fee basis, and that a physician's use of Trayslol did not increase the payment the hospitals sought, at least in the ordinary course. *See* Rel. Mot. at 5–6; Rel. SOF ¶¶ 5–9; Bayer Mot. at 5–9; Bayer SOF ¶¶ 4–9. In footnotes, Relator asserts potential narrow exceptions to the fixed-fee payment system; however, she cites no evidence that any of these theoretical exceptions was ever triggered by any use of Trasylol.

ARGUMENT

For three reasons, the Court should reject Relator's challenge to the fixed-fee claims and grant Bayer's motion for partial summary judgment. The Court should also reject Relator's effort to re-inject factual issues into the case without any evidence, after Relator agreed that the DRG issue presented a pure question of law justiciable at summary judgment.

I. Relator Has Not Identified A Single Claim For Trasylol.

As Bayer explained in its opening brief, Relator's challenge fails at step one: She has failed to identify a claim for payment for Trasylol. The Government has

explained that it "is not able to produce" any claims for Trasylol because Trasylol was "administered in the inpatient setting" and "Trasylol is not identified on the inpatient claim." *See* CMS Letter at 1-2 (Lustberg Decl. Ex. A). Trasylol may have been *used* in the surgical procedure (as were surgical gloves and syringes), but regardless of such use, the claim is for the surgical procedure. It is undisputed and indisputable that the use of Trasylol does not affect the claim form or the payment.

Relator's argument that "courts have routinely held that UBs [claim forms] submitted to Medicare for bundled DRG payment constitute claims for purposes of the False Claims Act" is thus a *non sequitur*. Rel. Mot. at 16. Bayer does not dispute that "UBs" are claims. The point is that they are not claims for Trasylol; they are claims for surgeries.

Despite this obvious infirmity in her case, Relator asserts that three cases support her position that a DRG claim for a medical procedure is simultaneously a claim for unidentified products, like Trasylol, which appear nowhere on the claim form and the cost of which is borne by the hospital. Rel. Mot. at 16–19. She is incorrect. None of the cases Relator cites supports her proposition.

First, in *Commonwealth ex rel. Martino-Fleming v. South Bay Mental Health Center, Inc.*, No. 15-13065-PBS, 2018 WL 4539683 --- F. Supp. 3d. ---- (D. Mass.

Sept. 21, 2018) ("*Martino-Fleming I*"),[1] the allegation was that mental-health clinics were employing persons who lacked the licenses necessary to provide the mental-health services *that were identified on the claim form and for which the defendant sought reimbursement*. *Id.* at *2. Because the mental-health services were identified on the claim form and the defendant sought payment for those services, *Martino-Fleming I* is inapposite; here, by contrast, Trasylol does not appear on the claim form and hospitals did not seek payment for it.

Relator's Trasylol challenge is nothing like the facts in *Martino-Fleming I*, but is analogous to a case in which the mental-health provider allegedly received a kickback for the couch used by patients while receiving mental-health treatment. That couch, like Trasylol, does not appear on the claim form; and use of the couch, like the use of Trasylol, has no impact on the Government fisc. Neither the couch nor Trasylol can trigger False Claims Act liability.

Next, Relator relies on *United States v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430 (E.D. Pa. 2004). Relator ignores the fact that there, "the Government allege[d] that Medco charged for services not rendered," *id.* at 442,

[1] The court in *Martino Fleming I* also issued a companion decision dealing with the private relator's claims (rather than the State's claims). *See U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, No. 15-13065-PBS, 2018 WL 4539684 (D. Mass. Sept. 21, 2018). Relator refers to this companion decision as *Martino-Fleming II*. *See* Rel. Mot. at 17. That decision contains a similar discussion and analysis. *See Martino-Fleming II*, 2018 WL 4539684, at *7.

which makes *Merck-Medco* not a DRG case but rather a typical case in which the defendant allegedly did not provide the services identified on the claim form.

The defense in *Merck-Medco* was that the Federal Employee Health Benefits Program had a "fixed annual contribution" and thus there was no harm to the Government fisc resulting from the alleged claims for payment from that program. But, as the court there held, "[t]he Government does not take any leftover funds in the FEHBP accounts and simply burn them for the taxpayers' amusement; sooner or later, those funds must be put to some use." *Id.* The court also noted the alleged financial impact on future years' contributions. *See id.* Because of the alleged impact on the public fisc, the court denied the motion to dismiss. *Id.* at 443.

Accordingly, if anything, *Merck-Medco* undermines Relator's argument, given the Court's holding that "claims that 'do not or would not cause financial loss to the government are not within the purview of the FCA.'" *Id.* at 442 (quoting *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2001)). Here, the use of Trasylol caused no financial loss to the Government. Indeed, as discussed, Trasylol was not even identified on the DRG claim and the amount of the claim was the same regardless of whether Trasylol was used.

The third decision Relator cites is inapposite as well. *See U.S. ex rel. Morris v. Crist*, No. C-2-97-1395, 2000 WL 432781 (S.D. Ohio Mar. 29, 2000) (unpublished). In *Morris*, the relator presented claims for payment "for research

costs that were incurred as the result of for-profit drug studies," even though a specific regulatory provision stated that "the costs incurred pursuant to the for-profit drug studies … are non-allowable costs for purposes of determining reimbursement under Medicare." *Id.* at *4-5 (citing 42 C.F.R. §413.90 (1996)). Relying on this provision, the court concluded that "a reasonable jury could find that the charges for the for-profit drug studies should have been offset on the bill as non-allowable charges and that [the defendant's] failure to do so constitutes a false claim, despite the fact that [the defendant] may have included the correct DRG code for each patient." *Id.* at *6. By contrast, here, Relator has identified no claim for payment for Trasylol or any Trasylol charges at all.

All Relator has established is that Trasylol might have been *used* in surgical procedures in which a DRG claim was filed. But, if mere use of a product were sufficient to trigger FCA liability, there would be no end to the number of items or services that could expose a company to treble damages and statutory penalties. This Court should reject that sweeping and unprecedented expansion of the FCA.

II. Relator Cannot Show That The DRG Claims Are False.

Relator's argument fails as well because she has identified nothing that is false. Relator has not clarified whether she is proceeding under a theory of express

certifications or implied certifications,[2] but either way, she cannot show falsity based on DRG claims.

As Bayer explained in its motion, the express certifications in claims and cost reports cited by Relator concern "the services listed" or the "services identified." Bayer Mot. at 16 (citing complaint). Trasylol is not "listed" or "identified." Indeed, the Government itself has acknowledged that Trasylol is "not identified" on the DRG claim. CMS Letter at 1–2 (Lustberg Decl. Ex. A). There is therefore no express falsity.

Nor can Relator rely on any implied certifications. In *Escobar*, the Supreme Court said that the implied certification theory could be a basis for liability because (1) "the claim does not merely request payment, but also *makes specific representations about the goods or services provided*" such that (2) the "failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those representations misleading half-truths." *Universal Health Svcs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2000 (2016) (emphasis added). Because Trasylol is not "listed" or "identified" on any claim form, no hospital made any "specific representation" about the drug.

[2] However, she has confirmed that she is proceeding under a theory of legal falsity. *See* Rel. Mot. at n.28.

Relator appears to be taking the position that whenever a hospital submits a DRG claim, it is implicitly making certifications about products that are not even referenced on the claim form and that have no effect on the Government's payment. Nowhere does Relator reveal what this purported implied certification states; nor does she cite a decision articulating such a certification. This Court should reject Relator's effort to create a new and undefined certification—and with it, a new and undefined basis for FCA liability—that is inconsistent with Supreme Court precedent.

III. Relator Cannot Prove Materiality.

Relator also cannot prove materiality. Relator agrees (as she must) that she has the burden of proof on materiality and that a claim is material only if it will have an "effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Rel. Mot. at 20 (quoting *Escobar*, 136 S. Ct. at 2002). To be material, the challenged action must "be capable of influencing the payment or receipt of money or property." *Escobar*, 136 S. Ct. at 2002.

But it is undisputed that neither the use of Trasylol nor any associated misrepresentations affected the Government's decision to pay the DRG claims. *See* Rel. Mot. 5–6; Rel. SOF ¶¶ 5–9; Bayer Mot. 5–9; Bayer SOF ¶¶ 4–9. Indeed, it was impossible for Trasylol to influence the Government's payment decision because—according to the Government—Trasylol was "not identified on the inpatient claim."

CMS Letter at 1–2 (Lustberg Decl. Ex. A). Under *Escobar*, this fact means Relator cannot prove materiality.

Further, regardless of whether Trasylol was used, the cost to the Government is the same. Relator herself has stated that the use of Trasylol "***HAS NO TO MINIMAL RELATIONSHIP TO REIMBURSEMENT***," because Medicare "***pays … one set payment regardless of resources used***." LS00010768 (Nov. 5, 2003) (Lustberg Decl. Ex. B) (emphasis in original). And, as the Third Circuit has held, "the submission of false claims to the United States government for approval which do not or would not cause financial loss to the government are not within the purview of the False Claims Act." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2001). Trasylol was a cost borne by the hospitals, much like lightbulbs, surgical gloves, and stiches.

Nonetheless, Relator suggests that she can show materiality by cobbling together a few "non-dispositive factors" that she has selectively extracted from passages in *Escobar* and taken out of context. Rel. Mot. at 21. According to Relator, these factors include whether the violation is "significant" and "goes to the essence of the bargain"; whether "the government took action in this or other cases when it had knowledge of similar violations"; and whether the violated "requirement is a condition of payment." *Id.*

But, the Supreme Court never established these factors as a test for materiality. To the contrary, *Escobar* clearly held that a false statement is immaterial unless it is "capable of influencing the payment or receipt of money or property." 136 S. Ct. at 2002. That is the test for materiality, and Relator cannot satisfy it.

If Relator's "non-dispositive factors" are to play any role at all, it is because they may help a court answer the question whether the allegedly false statement actually influenced the payment or receipt of money or property. But here there is no dispute that the challenged action was incapable of influencing the Government's payment decision, because the Government paid a fixed fee and Trasylol did not even appear on the claim form. Relator's "non-dispositive factors" are therefore irrelevant.[3]

Regardless, Relator cannot meet her own gerrymandered test. The alleged violations are neither "significant" nor "the essence of the bargain" because they have no effect on the Government fisc. The essence of the bargain is the underlying medical procedure, and the cost of that procedure does not change depending on the

[3] Relator claims that, "[f]ollowing *Escobar*, materiality must be analyzed holistically." Rel. Mot. at 21. It is not clear what Relator means by this statement. In any event, neither the Supreme Court nor the Third Circuit has ever required a "holistic" analysis, but whatever that phrase means, it cannot negate the Supreme Court's clear definition of materiality as "capable of influencing [] payment." *Escobar*, 136 S. Ct. at 2002. Moreover, none of the decisions Relator cites to support her "holistic" analysis argument involved DRG payments.

use of Trasylol. Further, the Government intentionally structured its fixed-fee policy so that it would be indifferent to the items or services used.

Nor does Relator point to any instance in which the Government "took action in this or other cases when it had knowledge of similar violations." Relator simply asserts that the Department of Justice has "taken numerous criminal and civil enforcement actions against drug companies" for violating the Anti-Kickback Statute and Medicare's reasonable-and-necessary requirement. Rel. Mot. at 21 & n.31 (citing press releases). But Bayer does not dispute that such violations may well be the basis for FCA or other liability in other circumstances. What Relator fails to identify is any instance in which the Government denied payment for a DRG claim when the purported violation *has no effect on the public fisc and the allegedly tainted item does not even appear on the claim form*. *See Escobar*, 136 S. Ct. at 2003-04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.").[4] For similar reasons, Relator's argument that Bayer violated a condition

[4] Although outside the scope of this motion, it is worth noting that the Government continued to pay DRG claims for years, even after it was fully aware of the allegations in Relator's complaint. Bayer, moreover, asked the Government to identify all claims related to Trasylol that it denied due to alleged kickbacks, and it produced none. Bayer Subpoena to CMS Request No. 1 (Aug. 17, 2018) (Lustberg Decl. Ex. O); CMS Letter at 1–2 (Lustberg Decl. Ex. A).

of payment falls flat. In any event, "[w]hether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry." *Id.* at 2001.

Indeed, Relator cites no cases supporting her position. The best she has come up with is *United States ex rel. The Dan Abrams Co. v. Medtronic, Inc.*, No. LA CV15-01212 JAK (ASX), 2017 WL 4023092 (C.D. Cal. Sept. 11, 2017), an unpublished decision which *granted* the defendant's motion to dismiss. *Id.* at *12. Because that case dismissed the complaint, Relator relies only on dictum. And because this dictum is in a section on causation, not materiality, *see id.* at *9 ("Sufficiency of Allegations that the Alleged Fraud Caused the Payment of Claims"), she stretches it beyond what the decision can bear. The decision contains only a passing reference to materiality, conflating it with causation and falsity. *See id.* at *9-10.[5] Further, the court did not conclude that the alleged false claim could survive summary judgment. The case arose on a motion to dismiss, so the court addressed only the pleading standard. *Dan Abrams* thus does not help Relator.

Neither does *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 394 (1st Cir. 2011). As Bayer explained in its motion, *Hutcheson* was issued before *Escobar*'s "heightened materiality standard," *U.S. ex rel. Petratos v.*

[5] The court's discussion is cryptic at best: "Thus, this claimed decision-making process does not mean that the government has not, in establishing general payment policies, has assigned no [sic] value to products that have been approved through an FDA process." *Id.* at *10.

Genentech Inc., 855 F.3d 481, 492 (3d Cir. 2017), was decided on a motion to dismiss not on summary judgment, and arose in a context in which the alleged misrepresentations may well have caused the Government to pay for surgeries that otherwise might not have occurred. *See* Bayer Mot. at 23–24. The situation with Trasylol, of course, is completely different and factually distinguishable. The surgeries in which Trasylol was used would have occurred regardless of Trasylol use, and the Government paid the same amount either way. Relator survived a motion to dismiss, as did the relator in *Hutcheson*; but, because Relator has presented no evidence supporting her allegations regarding materiality, she cannot survive summary judgment.

Relator's citations (without any discussion) to other decisions also miss the mark. Neither *United States ex rel. Cairns v. D.S. Medical, L.L.C.*, No. 1:12CV00004 AGF, 2017 WL 3781807, at *1 (E.D. Mo. Aug. 31, 2017), nor *United States v. Berkeley Heartlab, Inc.*, No. 9:14-230-RMG, 2017 WL 6015574, at *1–3 (D.S.C. Dec. 4, 2017), addressed the DRG issue at all. Moreover, in those cases, the physician received a kickback for items "that were to be paid for by a federal health care program." *Cairns*, 2017 WL 3781807, at *4; *see Berkeley*, 2017 WL 6015574 (kickback for lab services for which "the Government pays a claim"). Bayer does not dispute that such kickbacks might well be the basis for liability because of the

impact on the Government fisc.[6] But, here, the Government did not pay for Trasylol, and the drug did not even appear on the claim forms. Thus, the purported kickbacks (and the purported violation of the reasonable-and-necessary requirement) had no affect on the Government fisc, and the Government did not even know whether Trasylol was used in the procedure.

There is a reason why courts—including this Court—have consistently rejected Relator's position. *See* Bayer Mot. at 20–25. Where, as here, the Government pays a fixed fee for a procedure, and the allegedly tainted product has no effect on the treasury and does not even appear on the claim form, the alleged falsity is immaterial. The fact that many of the decisions rejecting Relator's argument came out "[b]efore *Escobar*," (Rel. Mot. n.29), does not limit their authority; to the contrary, as the Third Circuit has recognized, *Escobar* imposed a "heightened materiality standard," *Genentech Inc.*, 855 F.3d at 492, which is "demanding" and "rigorous," *id.* at 489; thus, materiality is more stringent now than

[6] Relator also cites *Merck-Medco* again, but as discussed above, it is irrelevant: it is not a DRG case, and the defendant allegedly charged for services not rendered. *See supra* at 6–7. Finally, Relator cites the Third Circuit's *Greenfield* decision. This is surprising because the Third Circuit did not address materiality, let alone materiality in the DRG context, *see U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 98 n.8 (3d Cir. 2018) (acknowledging that "distinct" question of materiality was not at issue), and the court *granted* summary judgment to the defendant; as here, the relator there could not "come forward with at least a 'single false [or fraudulent] claim' that the defendants submitted to the Government for payment." 880 F.3d at 99–100.

when those decisions were issued. Consistent with *Escobar*, these cases correctly rejected Relator's position, and this Court should do the same.

The FCA is not a blanket invitation for the private prosecution of all kickbacks and other alleged wrongdoing. *See Escobar*, 136 S. Ct. at 2003 ("[t]he "False Claims Act is not 'an all-purpose antifraud statute'") (quoting *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008)); *contra* Rel. Mot. at 22 (suggesting that "a medically dangerous item or an item tainted by kickback" is enough to trigger FCA liability). The statute requires actual claims, *Greenfield*, 880 F.3d at 99, actual misrepresentations, *Escobar*, 136 S. Ct. at 2000, and actual materiality, *id.* at 2002. In light of the undisputed facts regarding the Government's fixed-fee policy, Relator cannot show any of these. Her Trasylol causes of action therefore fail as a matter of law.

IV. Relator's Litany Of Purported Exceptions Cannot Save Her Trasylol Case.

This case has been pending for over a decade, and Relator has not identified a single example of any Government payment for Trasylol. In the Tenth Amended Complaint, she alleged the existence of exceptions to the fixed-fee policy, such as outlier payments, but despite issuing subpoenas to dozens of hospitals and states around the country, she has identified no evidence of any payments. *See* Bayer Mot. at 12–13 (citing discovery requests and responses). Nor did she produce any evidence at any of the conferences held by this Court. Now, in her brief, she again

fails to produce a single shred of evidence of any Government payment or impact on the fisc.

Nonetheless, in multiple footnotes, she continues to assert exceptions without evidence—even though she told the Court that the DRG policy presents a pure question of law, warranting immediate cross-motions for summary judgment. This Court should reject her belated efforts, buried in footnotes, to preserve arguments without evidence.

1. Outlier Payments And Inflation Of Future DRG Reimbursement

As Bayer predicted, Relator tries to maintain her Trasylol causes of action by relying on the mere conjectural possibility of outlier payments or inflation in future DRG reimbursements. *See* Rel. Mot. at n.27. Bayer explained in its motion why Relator's outlier and inflation arguments are illogical and unavailing. Bayer Mot. at 25–28. In addition, at the summary judgment stage, mere allegations are no longer sufficient. *U.S. ex rel. Kennedy v. Aventis Pharm., Inc.*, No. 03 C 2750, 2008 WL 5211021, at *4 (N.D. Ill. Dec. 10, 2008) (rejecting relator's outlier argument and granting summary judgment to defendant because "after nine months of discovery" the relator had identified no outlier payments). A party may not survive summary judgment by "hypothesizing"; there must be some "record evidence." *Greenfield*, 880 F.3d at 99–100. Because Relator has no evidence, and because any changes to

DRG payment rates must be *budget neutral*, *see* Bayer Mot. at 9, 26–27, this Court should reject her arguments.

2. Physician Services Medicare Part B Claims

Relator also contends that the parties' motions do not cover any physician-services claims made under Medicare Part B (as compared to Medicare Part A). Rel. Mot. at n.18. What Relator fails to note, however, is that physician-services claims under Part B also use a bundled-coding system, under which the code claimed for payment includes all services performed for the typical patient and does not vary with the presence or absence of a particular drug. *See* American Medical Association, *Current Procedural Terminology 2004 Standard Edition*, instructions for billing for Coronary Artery Bypass Grafts, pp. 108-109. The bill would not have contained any reference to Trasylol. *See* Medicare Claims Processing Manual, Chapter 17, Section 10 Payment Rules for Drugs and Biologicals.[7] Moreover, Relator has never identified any physician-services Part B claims, let alone provided any evidence why those claims are false and material.

3. Claims For Trasylol Administered Outside The Hospital Or In Specialty Hospitals

Relator asserts that the parties' motions do not reach "claims for the physician administration of Trasylol," Rel. Mot. at n.1, by which she apparently means claims

[7] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf

for Trasylol administered outside the hospital, *i.e.*, in a doctor's office. This is pure conjecture. Trasylol was a powerful blood-sparing drug used during particularly bloody surgeries; it would not have been administered in a doctor's office. Indeed, the applicable Medicare regulations require providers to perform the procedures in which Trasylol was principally used only in the hospital. *See, e.g.*, Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates, 68 Fed. Reg. 63398, 63656–63682 (Nov. 7, 2003); Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18434, 18779–18787 (Apr. 7, 2000). Moreover, Relator has not produced any evidence of a single physician-administered claim.

Nor has she produced evidence of any Trasylol claims from specialty hospitals, such as pediatric hospitals, which may not be governed by the Government's fixed-fee policy. Bayer has repeatedly asked Relator for any allegedly false claims for Trasylol that may have affected the Government fisc, but she has produced no evidence.

4. Medicaid Programs With Purported Exceptions To Fixed-Fee Policy

Relator admits that "State Medicaid programs also utilized some form of prospective payment system for inpatient services during the Relevant Time Period." Rel. Mot. at n.8; *see also id.* at n.26. But she claims that "some states did not apply the [prospective payment system] to all hospitals or treatments or only used this

system when actual costs were more than the fixed payment." *Id.* at n.8. Relator misunderstands the state laws upon which she purports to rely,[8] but the Court need not wade into these issues because Relator has pointed to no evidence showing that any state paid a single penny for Trasylol. At summary judgment, a party cannot rely on allegations of merely theoretical exceptions.

5. Violations of 31 U.S.C. § 3729 Subsections (a)(2) And (a)(7)

Finally, Relator asserts that the parties' motions do not implicate her Trasylol causes of action based on 31 U.S.C. § 3729 subsections (a)(2) and (a)(7). *See* Rel. Mot. n.1. This makes little sense. Like subsection (a)(1), these subsections require a Relator to establish a claim (or reverse claim), falsity, and materiality. *U.S. ex rel.*

[8] For instance, three of the States that Relator identifies as having "exceptions" simply used a fixed per-diem rate rather than a fixed per-discharge rate (as in the federal Medicare system). *See* Rel. Mot. at n.26 (citing per-diem programs in Florida, Louisiana, and Alaska). Of course, a per diem is just another type of fixed-fee policy, as Relator herself acknowledges. *Id.* Relator never explains how or why the use of Trasylol could affect the per diem in these States. Moreover, as the Florida provision makes clear, the per-diem approach still is based on "selected diagnosis-related groups." Fla. Stat. § 409.905(5)(a).

Furthermore, most States contract with private insurance companies to cover most of their Medicaid enrollees. *See generally* Centers for Medicare & Medicaid Services, Managed Care, https://www.medicaid.gov/medicaid/managed-care/index.html (describing State Medicaid managed-care programs). In this arrangement, the State pays a monthly or annual premium to the private insurance company; it does not actually pay for the medical care itself. *See id.* The State accordingly not only would not have paid for Trasylol, it would not even have paid for the procedure in which Trasylol was used (other than indirectly through its monthly or annual premium).

Spay v. CVS Caremark Corp., 875 F.3d 746, 761 (3d Cir. 2017); *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 (D.C. Cir. 2017); *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1052 (11th Cir. 2015); *U.S. ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1224 (11th Cir. 2012). Because Relator cannot satisfy any of these threshold elements, the Court should grant partial summary judgment to Bayer.

CONCLUSION

The Court should deny Relator's motion and grant Bayer's motion for partial summary judgment.

Dated: November 5, 2018

Respectfully submitted,

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